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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
08/476,630	06/07/95	DOBROGOSZ	W BIOA5063LBTG

18M2/1219

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EXAMINER	
MARX, I	
ART UNIT	PAPER NUMBER
1808	10

DATE MAILED: 12/19/96

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 41-45 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 41-45 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

– SEE OFFICE ACTION ON THE FOLLOWING PAGES –

★ U.S. GPO: 1996-409-290/40027

The application should be reviewed for errors.

The preliminary amendments filed 10/8/96, 6/7/96 and 11/14/95 are acknowledged. Claims 41-45 are being considered on the merits.

The numbering of claims is not accordance with 37 C.F.R. § 1.126. The original numbering of the claims must be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When claims are added, except when presented in accordance with 37 C.F.R. § 1.121(b), they must be renumbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not). Misnumbered claims 67-70 have been renumbered 41-44 respectively. Claim 46 was renumbered as 45.

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

The non-statutory double patenting rejection, whether of the obvious-type or non-obvious-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); In re Van Ornam, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and In re Goodman, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321 (b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78 (d).

Effective January 1, 1994, a registered attorney or agent of record may sign a Terminal Disclaimer. A Terminal Disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 41-45 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 5,534,253; claim 1 of U.S. Patent No. 5,439,678; claims 1-3 of U.S. Patent No. 5,458,875 and claims 6-8 of U.S. Patent No. 5,480,641. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the patents pertain to treating bacteria with *L. reuteri* that produce β-hydroxypropionaldehyde by administering such bacteria in various manners, including as a probiotic. It is noted that the presently claimed invention is not drawn to a specific method, such that it is unclear which bacteria are treated and at which location. Therefore, the claims are deemed to be co-extensive.

Claims 41-45 are rejected under 35 U.S.C. § 112, first and second paragraphs, as the claimed invention is not described in such full, clear, concise and exact terms as to enable any person skilled in the art to make and use the same, and/or for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 41 is vague and indefinite in the recitation of "storage conditions" in item (d). Is refrigeration intended? Anaerobic storage encompasses food vacuum packed in a can or package, lyophilized items, frozen items, etc.. The scope of the claim cannot be assessed from the context presented.

Claim 42 is confusing, since it is unclear what is intended by "treating non-Lactobacillus reuteri bacteria". What are these bacteria treated for? Where are they treated? Is this an *in vitro* or an *in vivo* process? How is the determination of the number of bacteria in the composition to be treated or in the body carried out? How long is the treatment intended to be carried out?

Growth and proliferation of bacteria takes time. However, a growth or incubation step is not included and a time frame not disclosed. Applicants have not provided an enabling disclosure for the treatment of any and all pathogenic bacteria that are non-*Lactobacillus reuteri* in any organism, including humans. If an *in vitro* process is intended, this material should be clearly claim designated.

Claim 43 is confusing in the recitation of "feeding the animal cells of said strain". To clarify the invention it is suggested that the claim be amended to recite -- feeding the animal an amount sufficient of *Lactobacillus reuteri* to colonize..-- Moreover, it is unclear that a sufficient enabling disclosure is provided for the number of microorganism cells required to colonize the gastrointestinal tract for any and all animals, including insects and protozoa, or that the required glycerol or glyceraldehyde concentration will be available for the production of β-hydroxypropionaldehyde. Are mammals intended?

Claim 45 is vague and indefinite in that the phrase "A method for reducing the number of bacteria and food item for animals" is not a proper claim preamble. It is also unclear what is intended by "reducing the number of bacteria **more** that does treatment with 250 mM glycerol or glyceraldehyde". How much more, 10%, 1% or 0.000001% more? The distinction in numbers reduced as compared with the control is also not understood. The terminology is ambiguous and open to interpretation. The nature of the bacteria to be reduced is unclear from the present context.

Claims 44-45 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the

art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

No basis or support is found in the present written disclosure for the recitation "applying about 200 μg of β-hydroxypropionaldehyde per gram of food item". Issues of new matter are raised because there is no clear support or basis in the as filed specification for the use of such amount of β-hydroxypropionaldehyde per gram of food item and for the reduction of the number of bacteria to be at least a 10^{-3}.

No clear basis or support is found for a multi-log factor decrease in the number of any non-*Lactobacillus reuteri* bacteria in any substrate or any anaerobic environment merely if a 10-fold less than the number of bacteria present of *L. reuteri* is added and a stated concentration of glycerol or glyceraldehyde precursor is present.

The amendment in the description of the drawings also raises the issues of new matter. Applicants failed to proffer clarification of Figures 13A and 13B as required. Even though, from the Brief Description of Drawings (page 8) it is apparent that these figures are reversed, Applicants' did not explain specifically what the basis is for the amendment.

Therefore the material claimed constitutes new matter and should be deleted.

Applicants' arguments are moot in view of the new grounds of rejection directed to the claims now under examination.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (703) 308-2922.

Serial Number: 08/476630
Art Unit: 1808

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Group 1800 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 308-0294.

Irene Marx
Primary Examiner
Art Unit 1808